

REMARKS

Claims 1, 4, and 7-17 stand rejected, and claims 2, 3, 5, and 6 are objected to. Applicants have amended claim 7 to remove the term "enriched," and have amended claim 18 for grammatical purposes. Applicants also have amended the claim of priority to related applications to clarify that the present application is a continuation of U.S. Serial No. 09/451,353, and to add a claim of priority to Provisional Application No. 60/110,516. No new matter has been added.

In light of these amendments and the following remarks, Applicants respectfully request reconsideration and allowance of claims 1-18.

Power of Attorney

Morrison Foerster has withdrawn as attorney of record. The signature of the undersigned agent constitutes a representation to the United States Patent and Trademark Office that under the provisions of 35 C.F.R. § 1.34 and the law, she is authorized to represent the Assignee.

Objection to the specification

The Examiner objected to the specification, asserting that the Cross-Reference to Related Applications does not mention that the instant application is a continuation of Serial No. 09/451,353 (the '353 application). Applicants have amended page 1 of the specification to clarify that the present application is a continuation of the '353 application. In light of this amendment, Applicants respectfully request withdrawal of the objection to the specification.

Rejection under 35 U.S.C. § 112

The Examiner stated that "claims 1, 3, 7, and 8-17" stand rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of written description. In light of the Examiner's comments, however, it appears that this rejection applies to claims 1, 4, and 7-17. The Examiner asserted that the antigen recited in the present claims lacks written description, because it "is characterized only by functional attributes," without relating the functional characteristics to structural requirements.

Applicants respectfully disagree. The instant specification adequately describes the presently claimed subject matter. For example, Applicants' specification discloses that the recited antigen is present on the membrane and in the cytoplasm of human melanoma cells, including nevi, primary melanoma cells, and metastatic melanoma cells, and is not detectably expressed in normal non-activated human melanocytic cells or in the human tumor cells lines listed in Table 2, as tested by the SM5-1 antibody. *See*, for example, page 4, lines 14-22. Applicants' specification also discloses methods for detecting the recited antigen in various melanocytic tissues, including melanomas and metastases. *See*, e.g., page 18, line 18 to page 19, line 6. Further, Applicants' specification discloses that the antigen is obtainable from natural sources, for example. In fact, Applicants' specification discloses that an antigen was immunoprecipitated from cell extracts, and produced a staining signal of about 200 kD apparent molecular weight. *See*, page 22, lines 6-8. Thus, a skilled artisan reading Applicants' specification would have appreciated that Applicants were in possession of the presently recited antigen.

Further, independent claims 1, 7, and 8 require the antigen to be structured such that it can be specifically bound by the recited antibody. Moreover, independent claims 1, 7, and 8 indicate that the recited antibody is an antibody produced by a hybridoma that was deposited with the American Type Culture Collection under ATCC Accession No. HB-12588. The Federal Circuit has held that a biological deposit can satisfy the written description requirement. For example, the court in *Enzo Biochem, Inc. v. Gen-Probe Incorporated* (323 F.3d 956 (Fed. Cir. 2002)) held that "reference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of § 112, paragraph 1."

In the present case, Applicants have placed a hybridoma producing the recited antibody in a public depository, and have disclosed in the specification a method for identifying the antigen bound by the antibody. As noted by the Federal Circuit and the USPTO Guidelines, antibody technology is well developed and mature. *See*, e.g., *Enzo* at 964. Given Applicants' disclosure and the knowledge in the art, a person of ordinary skill in the art would have appreciated that Applicants invented and were in possession of the presently claimed subject

matter at the time the instant application was filed. Thus, the pending claims meet the written description requirement.

In light of the above, Applicants respectfully request withdrawal of the rejection of claims 1, 4, and 7-17 under 35 U.S.C. § 112, first paragraph.

Rejections under 35 U.S.C. § 102

The Examiner rejected claim 7 under 35 U.S.C. § 102(b) as allegedly being anticipated by the Natali *et al.* reference (*Brit. J. Cancer* (1995) 71:1243-1247) as evidenced by the Trefzer *et al.* reference (*BMC Cancer* (2006) 6:1-12). The Examiner asserted that the Natali *et al.* reference discloses fibronectin isoforms in melanocytic lesions, and the Trefzer *et al.* reference discloses that monoclonal antibody SM5-1 recognizes a fibronectin variant that is widely expressed in melanoma and not confined to metastatic melanoma. The Examiner alleged that since claim 7 does not require that the antigen be separated from the cell, the sample of cells exhibiting the fibronectin variant constitutes an enriched antigen.

Applicants respectfully disagree. To further prosecution, however, claim 7 is amended herein to remove the term “enriched.” At no point does the Natali *et al.* reference disclose an isolated or purified antigen as recited in present claim 7. Thus, claim 7 is novel over the cited references.

In light of the above, Applicants respectfully request withdrawal of the rejection of claim 7 under 35 U.S.C. § 102(b).

Claim objections

The Examiner objected to claims 2, 3, 5, and 6 as being depended on a rejected base claim. The Examiner stated that these claims would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicants submit that in light of the remarks presented herein, independent claim 1 is in condition for allowance. Thus, amendments to claims 2, 3, and 5 are not warranted. Applicants respectfully note that claim 6 is an independent claim that should have been allowed. In light of the above, Applicants respectfully request withdrawal of the objection to claims 2, 3, 5, and 6.

Allowed claim

Applicants acknowledge the allowance of claim 18.

REMARKS

Applicants submit that claims 1-18 are in condition for allowance, which action is respectfully requested. The Examiner is invited to telephone the undersigned agent if such would further prosecution.

Please change \$1020 for the Petition for Extension of Time fee, and apply any other charges or credits, to deposit account 06-1050.

Respectfully submitted,

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